

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE) MDL NO. 1456
LITIGATION) Civil Action No. 01-12257-PBS

THIS DOCUMENT RELATES TO) Hon. Patti B. Saris
CLASS 1 RESIDENTS OF THE)
COMMONWEALTH OF)
MASSACHUSETTS)

**THE J&J DEFENDANTS' LOCAL RULE 56.1 STATEMENT IN SUPPORT OF THEIR
POST-REMAND MOTION FOR SUMMARY JUDGMENT AGAINST CLASS 1
RESIDENTS OF THE COMMONWEALTH OF MASSACHUSETTS**

Johnson & Johnson, Centocor, Inc., and Ortho Biotech Products, LP (the “J&J Defendants”) identify the following material facts of record as to which there is no genuine issue to be tried.

Undisputed Facts Concerning Knowledge of Spreads

1. Plaintiffs concede, and the Court found, that “it is undisputed that the market understood and expected a 20 to 25 percent formulaic markup from WAC to AWP.” *In re AWP*, 491 F. Supp. 2d at 91; *see also id.* at 40 (“[T]hroughout the class period, most knowledgeable insiders understood that AWP did not reflect the average sales price to providers, but that it bore a formulaic relationship to WAC of a 20 to 25 percent markup.”)

2. Plaintiffs concede, and the Court found, that “payors were aware there was some discounting from WAC.” *Id.* at 40. The formulaic markup, coupled with modest discounts, resulted in a marketplace expectation of spreads in the range of approximately 30%. *Id.* at 92 (finding that Dr. Hartman’s 30% yardstick was a reliable measure of marketplace expectations); *see also* Exh. 8¹ (11/21/06 Trial Tr.) at 120:17-23 (testimony by Dr. Hartman that his 30% yardstick generally reflected what “payors either understood or just basically took as for granted”).

3. Plaintiffs concede, and the Court found, that the government shared the market’s understanding of spreads in the range of 30%. *In re AWP*, 491 F. Supp. 2d at 32; *see also id.* at 40 (citing Dr. Hartman’s testimony that “government [and] policy makers” expected that “AWP did not exceed the average sales price by more than 30 percent”); Exh. 9 (11/20/06

¹ All “Exh.” cites are to the exhibits to the November 23, 2009 Declaration of Andrew D. Schau in support of this Motion.

Trial Tr.) at 118:19-21 (testimony by Dr. Hartman that “[t]he government has set reimbursement rates that reflect an understanding that is comparable to what I would say is – in my yardsticks”).

4. Plaintiffs concede that Dr. Hartman’s 30% liability yardstick is appropriately applied to Medicare. Exh. 9 (11/20/06 Trial Tr.) at 119:17-25, 120:1-19 (testimony by Dr. Hartman that his 30% liability yardstick was appropriately applied to Medicare); *see also* H.R. Rep. No. 108-178, pt. 2, at 194, 197-98 (2003) (“Congress has long recognized AWP is a list price and not a measure of actual prices.”)

5. According to Michael K. Loukes, former Chief of the Health Care Fraud Unit for the U.S. Attorney’s Office in Boston, Congress expected AWP to reflect a formulaic markup over WAC. *See* Exh. 10 (6/24/04 Hrg. Tr., *United States v. MacKenzie*, CR-01-10350-DPW (D. Mass)) at 67-68 (“As a matter fact, Your Honor, a historical fact ... everybody got the spread between AWP and list price, the same 25 percent.... And the 25 percent, everyone gets that. That’s there. *That’s what Congress expected with AWP.*” (emphasis added)).

Undisputed Facts Concerning the Spreads on Procrit® and Remicade®

6. Plaintiffs concede, and the Court found, that the spreads on Procrit were always less than 30%. *In re AWP*, 491 F. Supp. 2d at 56, 104.

7. Plaintiffs concede, and the Court found, that the spreads on Remicade “hovered very near to 30% throughout the class period.” *Id.* at 57.

8. Plaintiffs concede, and the Court found, that published AWPs for Procrit and Remicade closely tracked the average selling prices. *Id.* at 104.

9. Plaintiffs concede, and the Court found, that the spreads on Procrit and Remicade “never substantially exceeded the range of what was generally expected by the industry and the government.” *Id.* at 31.

Undisputed Facts Concerning Consumer Knowledge of Spreads

10. The consumers who testified at the Track One trial had never heard of AWP. *Id.* at 38.

11. Ms. Anna Choice testified at trial that she had no “knowledge regarding what AWP meant.” Exh. 11 (11/07/06 Trial Tr.) at 74:13-15.

12. Ms. Rebecca Hopkins testified at trial that she did not “know anything about AWP at all.” *Id.* at 107:23-25.

13. Mr. Young, the class representative for Remicade, testified at his deposition that he never heard of AWP, and that he did not know how or by whom AWP was calculated. Exh. 12 (11/09/05 Young Dep. Tr.) at 61.

14. Mr. Shepley, the class representative for Procrit, testified at his deposition that he was not familiar with AWP. Exh. 13 (11/11/05 Shepley Dep. Tr.) at 29:8-14.

Undisputed Facts Concerning the Absence of Damages

15. Plaintiffs concede that application of Dr. Hartman’s 30% yardstick to Procrit and Remicade yielded \$0 in damages for Medi-Gap insurers in Class 2. Exh. 14 (12/11/06 Trial Tr.) at 95:1-6.

16. By definition, the same 30% yardstick would yield \$0 in damages for Medicare beneficiaries in Class 1.

Dated: November 23, 2009

/s/ Andrew D. Schau

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CERTIFICATE OF SERVICE

I certify that on November 23, 2009 a true and correct copy of the foregoing was delivered via electronic service to all counsel of record pursuant to Case Management Order No. 2.

/s/ Andrew D. Schau
Andrew D. Schau